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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,315	10/29/2001	Robert V. Farese JR.	UCAL-105CIP2	1732

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,315

Applicant(s)

FARESE ET AL.

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/30/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1632

After further consideration, the previous office action mailed 08/27/2003, paper # 11, has been vacated and replaced with the instant office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 20-23, drawn to a non-human animal characterized by having a knockout allele of the naturally occurring, endogenous DGAT gene and a method of using an animal to test a candidate agent for DGAT function modulatory activity, classified in class 800;800, subclass 3;8.
- II. Claims 10-14 and 19 drawn to cells in vitro and an in vitro cellular assay for screening candidate agents for modulatory activity of DGAT function using said cells, classified in class 435;435, subclass 6;325.
- III. Claim 19 drawn to a cell free assay for screening candidate agents for modulatory activity of DGAT function, classified in class 435;435, subclass 6;325.
- IV. Claim 26, drawn to an in vitro, cellular assay for screening candidate agents for modulatory activity of DGAT expression, classified in class 435;435, subclass 7.21;6.
- V. Claim 26, drawn to an in vitro, cell-free assay for screening candidate agents for modulatory activity of DGAT expression, classified in class 435, subclass 6.
- VI. Claim 27, drawn to an in vivo assay for screening candidate agents for modulatory activity of DGAT expression, classified in class 424, subclass 9.2.

Art Unit: 1632

Claims 15-18 link(s) inventions I-III. The restriction requirement to the linked inventions I-III is subject to the nonallowance of the linking claim(s), claim 15-18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 24,25,28 and 29 link inventions IV-VI. The restriction requirement to the linked inventions IV and V is subject to the nonallowance of the linking claim(s), claims 24,25,28 and 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are

Art Unit: 1632

no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971).

See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the animals of Invention I can be used in in vivo screening assays to determine regulators of DGAT expression while the cells of Invention II can be used in in vitro assays to identify regulators of DGAT function in cells. The animals of Invention I are not necessary for the cells of Invention II and the cells are not necessary for the animal. The animals and the cells are structurally and functionally distinct with materially different uses and are classified separately. The burden required to search Inventions I and II together would be undue.

Invention I and III are patentably distinct because Invention I is drawn to an animal and methods of using the animal to screen candidate agents for modulation of DGAT function while Invention III is a cell-free in vitro screening assay to identify agents that modulate DGAT activity. The assays are independent and distinct with different methods steps, protocols, reagents and technical considerations. The animals and methods of Inventions I are not necessary for the methods of Inventions III. Inventions I and III are classified differently. The burden required to search Inventions I and III together would be undue.

Invention I and Invention IV or V are patentably distinct because Invention I is drawn to an animal and methods of using the animal to screen candidate agents for modulation of DGAT function while Inventions IV and V are drawn to in vitro assays for modulators of DGAT expression. The assays are independent and distinct with different methods steps, protocols,

Art Unit: 1632

reagents and technical considerations. The animals and assay using the animals of Inventions I are not necessary for the methods of Inventions IV or V. Inventions I, IV and V are classified differently. The burden required to search Invention I together with either Invention IV or V would be undue.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the animal of Invention I can be used to identify modulators of DGAT function while the methods of Invention IV are used to identify modulators of DGAT expression.

Inventions II and III are patentably distinct screening assays. The assays of Inventions II and III are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents.

Invention II and Inventions IV-VI are patentably distinct because Invention II is drawn to cells having a disrupted DGAT gene and an assay using the cells to screen candidate agents for modulation of DGAT function while Inventions IV-VI are screening assays to identify agents that modulate DGAT expression. The assays are independent and distinct with different methods steps, protocols, reagents and technical considerations. The assay of Invention II is not necessary for the assay of any of Inventions IV-VI and vice versa. Invention II and Inventions IV-VI are

Art Unit: 1632

classified differently. The burden required to search Invention II together with any of Inventions IV-VI would be undue.

Invention III and Inventions IV-VI are to cells having a disrupted DGAT gene and a cell-free screening assay to screen candidate agents for modulation of DGAT function while Inventions IV-VI are screening assays to identify agents that modulate DGAT expression. The assays are independent and distinct with different methods steps, protocols, reagents and technical considerations. The assay of Invention III is not necessary for the assay of any of Inventions IV-VI and vice versa. Invention III and Inventions IV-VI are classified differently. The burden required to search Invention III together with any of Inventions IV-VI would be undue.

Inventions IV-VI are patentably distinct, one from the other because each screening assay is independent and distinct with different methods steps, protocols, reagents and technical considerations. Invention IV uses cells, in vitro. Invention V is drawn to a cell free assay, in vitro. Invention VI is drawn to an in vivo assay. No invention is necessary one for the other, Inventions IV-VI are classified differently. The burden required to search any of Inventions IV-VI together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1632

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Note: After January 13, 2004, the Examiner may be reached at (571) 272-0725, and should the Examiner be unavailable, inquiries may be directed to Deborah Reynolds, SPE of Art Unit 1632 at (571) 272-0734.

PETER PARAS
PATENT EXAMINER



Valarie Bertoglio
Examiner
Art Unit 1632